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11 **IN THE UNITED STATES DISTRICT COURT**
 12 **FOR THE DISTRICT OF ARIZONA**

13 Clarence Wayne Dixon,

14 Petitioner,

15 vs.

16 The Arizona Department of Corrections,
 17 Rehabilitation & Reentry (ADCRR);
 David Shinn, Director of the Arizona
 18 Department of Corrections, Rehabilitation
 & Reentry; James Kimble, Warden, ASPC
 19 – Eyman,

20 Respondents.

CV22-00743-PHX-DJH-JFM

DEATH-PENALTY CASE

**Complaint for Equitable, Injunctive
 and Declaratory Relief [42 U.S.C. §
 1983]**

22 **I. Nature of Action**

23 1. Plaintiff Clarence Wayne Dixon brings this action pursuant to 42 U.S.C. § 1983
 24 for violations by the Arizona Department of Corrections, Rehabilitation and Reentry
 25 (“ADCRR”), of Plaintiff’s First Amendment right of access to governmental proceedings
 26 in the execution context, and his right to due process under the Fourteenth Amendment
 27 to the United States Constitution.
 28

2. Plaintiff is scheduled to be executed on May 11, 2022, by lethal injection and alleges that ADCRR intends to carry out his execution without disclosing whether the pentobarbital intended for use in his execution has been assigned a Beyond Use Date (“BUD”) after his scheduled execution date and will not be expired.

3. The written execution procedures issued by ADCRR prohibit the department from using a drug that has an expiration or BUD that is after the date an execution is carried out. Ariz. Dep’t of Corr., Rehab. & Reentry, Dep’t Order 710—Execution Procedures, Attachment D at 2 (Mar. 10, 2021), https://corrections.az.gov/sites/default/files/policies/700/0710_031021.pdf (“DO 710”).

4. In April 2021, Arizona initiated execution warrant proceedings for Plaintiff, and informed him that the State intended to use compounded pentobarbital and claimed the drug would have a 90-day BUD from the date of compounding. Motion to Set Briefing Schedule for Motion for Warrant of Execution, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. April 6, 2021). However, subsequently, the State admitted that the pharmacist retained to compound the drugs “revised that opinion and has advised ADCRR that, until certain specialized testing of a sample batch is conducted,” the pentobarbital would only have a 45-day BUD.¹ Motion to Modify Briefing Schedule at 2, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. June 22, 2021). The State explained that unless the BUD was extended beyond 45 days, the drugs would be unusable in an execution because the timeline between the initiation of the warrant procedure and the date an execution can be scheduled exceeds 45 days. *Id.* at 2-3.

5. In January 2022, the State again initiated warrant proceedings for Plaintiff, claiming that “specialized testing” had been completed and again asserting that the BUD of the drug was at least 90 days from the date of compounding. Motion to Set Briefing Schedule for Motion for Warrant of Execution, *State of Arizona v. Clarence Wayne*

¹“The “specialized testing” would not only need to be conducted, however; it would also need to demonstrate that a 90-day BUD was supportable based on the results of the testing.

1 *Dixon*, No. CR-08-0025-AP (Ariz. Jan. 5, 2022). The Arizona Supreme Court issued a
2 warrant of execution for Plaintiff on April 5, 2022. Warrant of Execution, *State of*
3 *Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. April 5, 2022).

4 6. ADCRR has produced eight heavily-redacted pages of drug testing results from
5 unidentified batches of compounded pentobarbital that purport to establish a BUD in
6 excess of 90 days, although none of the documents identify either the date the drug was
7 compounded or an assigned BUD. As described more fully below, these testing results
8 are insufficient to assign the expiry of the compounded pentobarbital, or to extend the
9 BUD beyond 45 days, the outer limits for sterile injectables based on pharmacy
10 compounding standards.

11 7. Plaintiff, through counsel, has diligently sought information from ADCRR
12 regarding the BUD of the drug intended for use in his execution, and the supporting
13 scientific data.

14 8. As of May 2, 2022, ADCRR has not provided Plaintiff with the requested
15 information regarding the BUD.

16 9. ADCRR's demonstrated refusal to provide Plaintiff with the requested
17 information violates his First Amendment right of access to governmental proceedings
18 and his right to due process guaranteed by the Fourteenth Amendment because it prevents
19 him from determining whether ADCRR is capable of carrying out his death sentence in
20 accordance with the execution procedures set forth in DO 710 and his constitutional
21 rights.

22 10. Accordingly, Plaintiff seeks (a) a preliminary and permanent injunction
23 preventing ADCRR from executing him until the department has demonstrated that the
24 compounded pentobarbital has been assigned a BUD or expiration date beyond the date
25 of his scheduled execution that is based on scientifically-valid specialized testing; and
26 (b) an order declaring that executing him without providing this information violates his
27 First Amendment rights and his right to due process under the Fourteenth Amendment to
28 the U.S. Constitution.

1 11. This Complaint does not challenge Plaintiff's underlying capital conviction or
2 sentence of death, nor does it allege that his execution is per se unconstitutional.

3 **II. Jurisdiction and Venue**

4 12. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), 28
5 U.S.C. § 1343 (civil rights violations), 28 U.S.C. § 2201 (declaratory relief), and 28
6 U.S.C. § 2202 (injunctive relief). Plaintiff invokes this Court's jurisdiction pursuant to
7 Article III of the United States Constitution, the Fourteenth Amendment to the United
8 States Constitution, and 42 U.S.C. § 1983.

9 13. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b). Plaintiff
10 is currently incarcerated at the Arizona State Prison Complex ("ASPC") Eyman-
11 Browning Unit, 4374 East Butte Avenue, Florence, Arizona, 85132, located in this
12 District.

13 **III. Parties**

14 14. Plaintiff Clarence Wayne Dixon is a United States and Arizona citizen, and
15 member of the sovereign Navajo Nation. Plaintiff is incarcerated at ASPC Eyman-
16 Browning Unit in Florence, Arizona.

17 15. Plaintiff is currently under a warrant of execution and is scheduled to be executed
18 on May 11, 2022, at ASPC—Florence within the State of Arizona and within this District.

19 16. Defendant David Shinn is the Director of ADCRR and is being sued in his official
20 capacity for equitable, injunctive, and declaratory relief. Director Shinn oversees all
21 ADCRR operations and signed the current version of DO 710.

22 17. Defendant James Kimble is the Warden of ASPC Florence where Plaintiff's
23 execution is scheduled to take place. Under DO 710, the Warden of ASPC Florence
24 serves as the Housing Unit 9 Section Leader and is responsible for verifying that ADCRR
25 "will only use chemicals in an execution that have an expiration or beyond-use date that
26 is after the date that an execution is carried out." DO 710 § 3.2.2.3; Attachment D at 1.

27 18. Defendants John Does, Unknown ADCRR Personnel, are staff or agents of
28 ADCRR or the State of Arizona who are ADCRR's officers, successors in office, agents,

1 contractors, and employees, along with those acting in concert with them, who have
 2 participated or will participate in Plaintiff's execution with an expired execution drug.
 3 Plaintiff is not aware of the true identities of John Does, but alleges that when Plaintiff
 4 discovers their identities, Plaintiff will amend this Complaint accordingly.

5 **IV. Exhaustion of Administrative Remedies**

6 19. Plaintiff does not believe that exhaustion is necessary under the Prison Litigation
 7 Reform Act ("PLRA"), 42 U.S.C. § 1997e, because this suit does not challenge prison
 8 conditions and because there are no available administrative remedies that could address
 9 the challenged constitutional violation.

10 20. As described more fully below, Plaintiff, through his counsel, has diligently
 11 pursued information regarding the compounded drug intended for use in his execution,
 12 specifically the BUD and specialized testing on which it is established.

13 21. To date, Defendants have failed to provide Plaintiff with the information requested
 14 regarding the BUD and specialized testing.

15 **V. Factual Background**

16 22. Plaintiff was convicted and sentenced to death by the State of Arizona in 2008.
 17 *State v. Dixon*, 226 Ariz. 545, 548 ¶ 1, 250 P.3d 1174, 1177 (2011).

18 23. On April 5, 2022, the Arizona Supreme Court issued a Warrant of Execution,
 19 setting the execution date for May 11, 2022. Warrant of Execution, *State of Arizona v.*
 20 *Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. April 5, 2022).

21 **1. Arizona's Execution Statute and Execution Protocol**

22 24. Arizona Revised Statute § 13-757(A) provides that "[t]he penalty of death shall
 23 be inflicted by an intravenous injection of a substance or substances in a lethal quantity
 24 sufficient to cause death, under the supervision of the state department of corrections."
 25 Additionally, a prisoner like Plaintiff, who was "sentenced to death for an offense
 26 committed before November 23, 1992, shall choose either lethal injection or lethal gas at
 27 least twenty days before the execution date. If the defendant fails to choose either lethal
 28 injection or lethal gas, the penalty of death shall be inflicted by lethal injection." Ariz.

1 Rev. Stat. § 13-757(B). Plaintiff declined to elect a method of execution and his execution
2 will be carried out by lethal injection.

3 25. ADCRR establishes the written procedures for carrying out executions by lethal
4 injection in DO 710. The current version of DO 710 became effective on April 20, 2022.
5 *See* DO 710.

6 26. DO 710 provides that ADCRR can carry out executions with a drug protocol of
7 five grams of either sodium pentothal (thiopental) or pentobarbital and the Director has
8 the sole discretion to determine which protocol to use. DO 710, Attachment D at 2-3. DO
9 710 also provides that ADCRR can use a compounded version of the drug. *Id.*

10 27. DO 710 prohibits ADCRR from using a drug that is past the expiration date or
11 BUD to carry out an execution. *Id.* at 1.

12 28. DO 710 provides no information and requirements for how the pentobarbital
13 Defendants intend for use in Plaintiff's execution has been or will be compounded,
14 including no requirement that the drug is properly compounded in accordance with
15 applicable standards and best practices and by a qualified and licensed pharmacist.

16 29. The protocol is silent regarding the criteria for determining the BUD and what
17 process is required to extend the BUD.

18 30. DO 710 requires the State to provide notice to the prisoner whether a compounded
19 or non-compounded drug will be used at the time the State files a request for a Warrant
20 of Execution. The State must also provide the prisoner a "quantitative analysis of any
21 compounded or non-compounded chemical to be used in the execution shall be provided
22 upon request within ten calendar days after the state seeks a Warrant of Execution." *Id.*
23 at 2.

24 **2. The State located a source of compounded pentobarbital and initiated**
25 **the process of seeking Plaintiff's execution warrant in the Arizona**
Supreme Court

26 31. In early March 2021, a media article reported that the State had obtained
27 pentobarbital for use in executions. Jacques Billeaud, *Arizona finds death penalty drug*
28 *after hiatus in executions*, The Associated Press, Mar. 5, 2021 (available at

1 [https://apnews.com/article/arizona-phoenix-executions-](https://apnews.com/article/arizona-phoenix-executions-6f0ce846e174119635509e0c16b9ac1d)
2 [6f0ce846e174119635509e0c16b9ac1d](https://apnews.com/article/arizona-phoenix-executions-6f0ce846e174119635509e0c16b9ac1d)).

3 32. The next month, on April 6, 2021, the State sought a briefing schedule from the
4 Arizona Supreme Court for its anticipated motion for a warrant for Plaintiff's execution.
5 Motion to Set Briefing Schedule for Motion for Warrant of Execution, *State of Arizona*
6 *v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. Apr. 6, 2021). In this motion, the
7 State claimed—without any support—that the drug to be used in Plaintiff's execution
8 would have a 90-day BUD. *Id.* at 2.

9 33. On June 22, 2021, the State requested modification of the briefing schedule
10 because its compounding pharmacist had revised the information about the BUD of the
11 compounded pentobarbital. Motion to Modify Briefing Schedule, *State of Arizona v.*
12 *Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. June 22, 2021). Whereas the State
13 originally claimed that “based on current testing” by its compounder “the drug has a
14 beyond-use date (aka expiration date) of 90 days from the date of compounding” (2021
15 Mot. to Set Briefing Schedule at 2), the actual shelf life of the compounded drug had a
16 drastically shorter shelf life of only 45 days (*see* Mot. to Modify Briefing Schedule at 2).
17 The State explained that unless the specialized testing extended the BUD beyond 45 days,
18 the drug would be unusable in an execution because the timeline between the initiation
19 of the warrant procedure and the date an execution can be scheduled exceeds 45 days. *Id.*
20 at 2-3.

21 34. On July 12, 2021, the Arizona Supreme Court denied the State's motion to modify
22 the warrant briefing schedule and ordered that “[t]he State may renew its scheduling
23 motion after specialized testing to determine a beyond-use date for compounded doses of
24 the drug.” Order, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz.
25 July 12, 2021).

26 35. On January 5, 2022, the State again initiated warrant proceedings for Plaintiff and
27 filed a motion with the Arizona Supreme Court seeking a briefing schedule for the motion
28 for a warrant of execution. The State claimed that “specialized testing” had been

1 completed and again asserted—again without evidence—that the BUD of the drug was
2 at least 90 days from the date of compounding. Motion to Set Briefing Schedule for
3 Motion for Warrant of Execution at 2, *State of Arizona v. Clarence Wayne Dixon*, No.
4 CR-08-0025-AP (Ariz. Jan. 5, 2022).

5 36. The supreme court set a briefing schedule and, in accordance with that schedule,
6 the State filed a motion for warrant of execution on February 24, 2022. Motion for
7 Warrant of Execution, *State of Arizona v. Clarence Wayne Dixon*, No. CR-08-0025-AP
8 (Ariz. Feb. 24, 2022).

9 37. At this time, the State informed Plaintiff that compounded pentobarbital would be
10 used to carry out his execution. Letter, Sparks to Plaintiff's Counsel, Feb. 24, 2022.

11 38. On February 25, 2022, under Department Order 710, Attachment D, counsel for
12 Plaintiff requested that the State produce within ten calendar days a *quantitative* analysis
13 of the compounded pentobarbital the State intends to use if an execution date were
14 scheduled for Plaintiff.

15 39. On March 4, 2022, the State produced a heavily redacted single page test result
16 that is not a quantitative analysis (*see* Expert Report of Michaela Almgren, PharmaD,
17 MA, March 10, 2022 (“Almgren Report”) ¶ 14) (Ex. 1), and indicates *only* that the
18 substance contains pentobarbital.

19 40. That document does not provide a BUD for the drug.

20 41. In response to the very limited information released, counsel for Plaintiff
21 requested that the State produce all documents related to the specialized testing of its
22 compounded pentobarbital, including all documents related to the BUD. Email Bass to
23 Sparks, Mar. 4. 2022.

24 42. On March 15, 2022, the State produced three heavily redacted pages of lab reports
25 from an unidentified batch or batches of compounded pentobarbital. These test results
26 did not identify when the drug or drugs were compounded, what significance the tests
27 had to the drugs intended for use in Mr. Dixon's execution, and did not provide an
28 assigned BUD.

1 43. On April 5, 2022, the Arizona Supreme Court issued a warrant of execution for
 2 Plaintiff and set his execution for May 11, 2022. Warrant of Execution, *State of Arizona*
 3 *v. Clarence Wayne Dixon*, No. CR-08-0025-AP (Ariz. April 5, 2022).

4 44. On April 14, 2022, the State produced four additional pages of redacted laboratory
 5 test results responsive to Plaintiff's counsel's March 4, 2022 request. The results did not
 6 identify whether the analysis was performed on the drug intended for use in Plaintiff's
 7 execution or some other batch of pentobarbital. The test results provided data regarding
 8 sterility, pH, and drug potency, but did not identify the date of compounding and did not
 9 provide an assigned BUD.

10 **3. Plaintiff has diligently sought information about the BUD assigned to**
 11 **the compounded pentobarbital intended for use in his execution**

12 45. Since the State of Arizona announced in March 2021 that it had identified a source
 13 of pentobarbital, Plaintiff, through counsel, has diligently sought information about the
 14 State's supply of pentobarbital, including the assignment of the drug's BUD and
 15 supporting scientific documentation.

16 46. On March 8, 2021, the Office of the Federal Public Defender, Capital Habeas Unit
 17 ("FPD"), sent a letter to Director Shinn seeking information about Defendants' supply of
 18 pentobarbital. Letter, Baich to Shinn, Mar. 8, 2021.

19 47. On May 13, 2021, ADCRR produced some records responsive to the FPD's
 20 request, including execution training documents, documents related to the refurbishment
 21 of the gas chamber, and a \$440,000 invoice for "pharmaceutical consultation services."
 22 ADCRR did not produce any information regarding the expiration date or BUD related
 23 to the supply of pentobarbital.

24 48. On July 21, 2021, after the supreme court denied the State's motion to modify the
 25 briefing schedule, counsel for Plaintiff requested information from Defendants regarding
 26 the supply of pentobarbital, including the "specialized testing" referenced in the State's
 27 June 2, 2021, Motion to Modify Briefing Schedule and documents, laboratory results,
 28 testing standards, timelines, and protocols related to the BUD, specifically the extension

1 of the BUD beyond 45 days. Letter, Baich to ADCRR Public Information Officer, Jul.
2 21, 2021.

3 49. In response to this request, the State produced a combination of previously
4 produced documents and new documents. The release included heavily redacted drug
5 purchase documents, execution training materials, and two lab reports indicating only
6 that the substance tested contained pentobarbital. None of the documents provide any
7 information about the BUD of the compounded pentobarbital or the testing protocols
8 Defendants' pharmacist would use or rely on to set and extend the BUD beyond 45 days.

9 50. As discussed above, on February 25, 2022, after the State filed the Motion for a
10 Warrant of Execution, Plaintiff requested that the State produce a quantitative analysis
11 of the compounded pentobarbital as set forth in DO 710.

12 51. The State produced a single heavily redacted page that did not include any BUD-
13 related information.

14 52. On March 4, 2022, as discussed above, Plaintiff's counsel requested additional
15 information about the "specialized testing" relied on by the State to extend the BUD.

16 53. On March 15, 2022, the State produced three additional, heavily redacted pages
17 that did not include any BUD-related information.

18 54. On April 14, 2022, counsel for Plaintiff, again emailed counsel for Defendants,
19 and specifically asked for documentation regarding the BUD assigned to the compounded
20 pentobarbital intended for use in Plaintiff's execution. Email, Bass to Sparks, April 14,
21 2022.

22 55. On April 22, 2022, Sarah Greener, ADCRR's Attorney General Liaison,
23 responded by telephone that she was working on producing documents responsive to the
24 request for BUD information and anticipated providing that information to Plaintiff
25 sometime in the next week.

26 56. As of May 2, 2022, the State has not produced any documentation or supporting
27 scientific data for the BUD assigned to the compounded pentobarbital intended for use
28 in Plaintiff's execution.

1 57. According to compounding guidelines, as discussed below, the drugs intended for
 2 use in Plaintiff's execution should have been assigned a BUD at the conclusion of the
 3 compounding process.

4 58. Due to Plaintiff's advanced age and declining health he is at an increased risk that
 5 subpotent or otherwise compromised drugs will increase the chance that he experiences
 6 pain and suffering during his execution. This is because his "heart, lungs and liver all
 7 show damage that likely will alter the way the [execution] drug is both delivered and
 8 metabolized." Declaration of Tara Cuccinelli, April 21, 2022 at 3 (Ex. 3). "His lungs,
 9 liver and heart are damaged enough that it might take longer to circulate the medication
 10 to reach full toxicity dose leaving him feeling some of the effects of Pentobarbital but not
 11 all of them." *Id.* at 3.

12 **4. Defendants have not provided Plaintiff the same type of information it**
 13 **has previously provided.**

14 59. The information regarding the BUD sought by Plaintiff is the same type of
 15 information Defendants have previously provided.

16 60. In July 2011, in response to a public records lawsuit, Defendants² released
 17 information about its supply of sodium thiopental, including the expiration dates of the
 18 drug. *Office Fed. Public Def. D. Ariz. v. Ariz. Dep't Corr.*, No. LC 2011-000344-001DT
 19 (Maricopa Cnty. Super. Ct. May 19, 2011).

20 61. In August 2011, during discovery relating to a suit by death-row prisoners,
 21 Defendants³ provided the Office of the Federal Public Defender with discovery materials
 22 containing detailed information about its supply of manufactured pentobarbital; that
 23 information included the expiration date of the drug. *See* Defs' Disclosures, Bates No.
 24 01985 DFS' 26(a)(1) Disclosures and Responses to RFPs, (Nembutal® Purchase Order);
 25 Defs' Disclosures, Bates No. 01973-01978 DFS' 26(a)(1) Disclosures and Responses to
 26

27
 28 ² "Defendants" here refers to predecessors to the current defendants; however, all are
 officials of the State.

³ *See* footnote 2.

1 RFP's, (Photographs of pentobarbital supply), *West v. Brewer*, No. 2:1 l-cv-01409-NVW
2 (D. Ariz.), Aug. 19, 2011.

3 62. In 2013, in another suit by death-row prisoners, after this Court ordered
4 Defendants⁴ to provide expiry dates and other information about its supply of
5 manufactured pentobarbital; Defendants complied. Order, *Schad v. Brewer*, 2:13-cv-
6 02001-ROS (D. Ariz. Oct. 4, 2013); [Defs'] Notice of Disclosure, *id.*, Oct. 5, 2013
7 (submitting information "over objection").

8 **5. Requirements for compounded drugs**

9 63. Pharmacy compounding is a practice in which a licensed pharmacist combines,
10 mixes, or alters ingredients of a drug to create a medication that is tailored to the specific
11 medical needs of a patient. "Human Drug Compounding," U.S. Food & Drug
12 Administration, [https://www.fda.gov/drugs/guidance-compliance-regulatory-](https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding)
13 [information/human-drug-compounding](https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding) (last visited Apr. 30, 2022).

14 64. In general pharmacy compounding, drugs can only be compounded upon the
15 receipt of a valid patient-specific prescription, among other requirements.
16 "Compounding Laws and Policies," U.S. Food and Drug Administration,
17 <https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies>
18 (last visited Apr. 30, 2022).

19 65. Compounded drugs are not approved by the Food and Drug Administration (FDA)
20 and are subject to less rigorous regulation and oversight relating to the identity, purity,
21 and potency of the drug than are manufactured drugs. *See id.*

22 66. The process of compounding drugs must meet the requirements contained in the
23 United States Pharmacopeia (USP). *See Almgren Report* ¶ 9.

24 67. The USP is a compendium of quality requirements, quality specifications,
25 practices, and guidelines to achieve the highest pharmaceutical quality for pharmacy
26 practice as well as the pharmaceutical industry. *See Almgren Report* ¶ 9.

27
28 ⁴ See footnote 2.

68. According to the USP, medications intended for intravenous injection are required to be sterile. *See* USP, General Chapter ,797, available at <https://www.usp.org/compounding/general-chapter-797> (last visited Apr. 30, 2022).

69. Sterile injectables must be compounded under aseptic conditions and in accordance with best practices to maintain sterility and a compounding environment free from contamination. *See* Almgren Report ¶ 8.

70. Compounded drugs are prepared using Active Pharmaceutical Ingredients (API), which are not typically sterile, which requires drug sterility testing to ensure the drug is not contaminated. *See* Almgren Report ¶ 12.

71. Compounded drugs have an expiry date known as a “beyond use date” (BUD), which is significantly shorter than the expiration date for commercially available products because compounded drugs do not undergo the same extensive quality testing. *See* Almgren Report ¶ 10.

72. BUDs are established by USP. According to USP, the maximum BUD for compounded sterile preparations like compounded pentobarbital are:

- 24 hours, if stored at room temperature;
- 72 hours, if kept refrigerated; or
- 45 days, if kept in a solid, frozen state.

Almgren Report ¶ 10.

73. BUDs must be assigned by the compounder and must appear on the label. USP, General Chapter < 797> Pharmaceutical Compounding—Sterile Preparations (“USP <797>”), at “Identity and Strength Verification of Ingredients”

74. Stability studies must be performed in order to extend the expiry for compounded drugs beyond the BUD established by the USP. *See* Almgren Report ¶ 11. Guidelines for performing adequate stability studies are set forth in FDA guidance documents. The guidelines typically require testing multiple samples stored under specified conditions and tested at regular intervals to determine if changes to the drug quality occurs, which

1 would signal that a drug expired, and the pharmacological action cannot be guaranteed.

2 *See id.* ¶ 11.

3 75. Stability studies are carefully designed to assure the drug maintains integrity and
4 pharmacological properties over time. *See* Supplemental Report of Michaela Almgren,
5 PharmaD, MA, March 31, 2022 (“Almgren Suppl. Report”) ¶ 6 (Ex. 2). Stability study
6 design must be specified in a test protocol that applies to the specific compounding
7 process, formulation or recipe, container closures system, storage conditions, and batch
8 size. *See id.* ¶ 7. A new stability study must be performed if any of these factors change
9 between batches. *See id.*

10 76. Stability studies are also typically performed by testing multiple samples of a
11 compounded drug from at a minimum of three different batches. Almgren Suppl. Report
12 ¶ 8.

13 77. Stability study tests are also performed at specific timing intervals, for example at
14 the point the drug is compounded and then monthly, to establish an understanding of the
15 drug’s degradation process over time. Almgren Suppl. Report ¶ 11.

16 78. Once compounded, sterile injectables must be stored under proper conditions,
17 defined by the USP or a stability study, or the drugs can become damaged, unusable, and
18 unsafe leading to unpredictable results and pain and suffering. Almgren Report ¶ 21.

19 79. Compounding of sterile injectable pentobarbital is a complex and highly
20 specialized process that requires specialized equipment, numerous pharmaceutical-grade
21 ingredients, chemical adjustments during the process, and, of course, the appropriate
22 experience and credentials in aseptic compounding technique. *See* Almgren Report ¶¶
23 26-27.

24 80. Even minor deviations from the complex procedures for compounding
25 pentobarbital can impact the safety and efficacy of the drug including resulting in
26 insufficient potency. *See* Almgren Report ¶ 28.

1 81. For these reasons, there is a substantial risk that compounded drugs generally, and
2 pentobarbital specifically, will be contaminated, handled improperly, or suffer from
3 quality issues, the most common and concerning of which is lack of potency.

4 82. These risks increase if the drug is used past the assigned BUD. Expired drugs can
5 have unpredictable pharmacological effects due to loss of potency and degradation. *See*
6 Almgren Report ¶ 5.

7 83. The use of contaminated, impure, or sub-potent compounded pentobarbital
8 “creates the risk that these drugs will not be sufficiently effective and will not have the
9 necessary pharmacological effect.” Almgren Report ¶ 35.

10 **6. Issues with ADCRR’s compounded pentobarbital**

11 84. Arizona intends to use an intravenous injection of compounded pentobarbital to
12 execute Plaintiff.

13 85. The injected formulation must be sterile. USP, General Chapter< 797>
14 Pharmaceutical Compounding—Sterile Preparations, (“USP <797>”).

15 86. The sterile injectable must have a properly determined BUD. USP <797> at
16 “Storage and Beyond-Use Dating”

17 87. The sterile injectable must be labeled with the BUD. USP <797> at “Identity and
18 Strength Verification of Ingredients”

19 88. The limited test results produced by the State are inadequate to assign an expiry
20 to the compounded pentobarbital, let alone extend a sterile injectable beyond 45 days
21 because they do not provide the required information needed to determine a drug’s
22 expiration date. *See* Almgren Suppl. Report ¶ 5.

23 89. The limited test results lack many basic elements of typical stability study for
24 compounded sterile injectables, including information about the study design and
25 parameters; the examination of multiple samples from multiple batches; the specific
26 compounding recipe used to prepare the compound; and the timing intervals for the tests.
27 *See* Almgren Suppl. Report ¶¶ 6-11.

1 90. The limited test results also fail to include data regarding the API and whether it
 2 contained any impurities that can effect the pharmacology of the finished product.
 3 Almgren Suppl. Report ¶ 22.

4 **7. Arizona intends to execute Plaintiff without providing documentation**
 5 **of the BUD of the compounded pentobarbital intended for use in his**
 6 **execution**

7 91. Despite requests by Plaintiff's counsel, Defendants have not provided
 8 documentation that establishes the BUD, based on scientifically valid specialized testing,
 9 of the compounded pentobarbital intended for use in his execution.

10 92. Defendants have only produced eight heavily redacted testing documents without
 11 identifying how those results relate to the compounded pentobarbital intended for use in
 12 Plaintiff's execution or how those test results provide the scientific basis for assigning
 13 the compounded pentobarbital an expiry.

14 93. Defendants intend to carry out Plaintiff's May 11, 2022, execution without
 15 providing him with data and documentation that establishes that the drug intended for
 16 use in his execution has been assigned a BUD that is beyond the date of his execution
 17 and is therefore not expired, in violation of DO 710.

18 **Claims for Relief**

19 **Claim One: Defendants' refusal to provide documentation regarding the BUD**
 20 **of the compounded pentobarbital intended for use in his execution violates**
 21 **Plaintiff's First Amendment right to be informed about the manner in which**
 22 **Defendants implement his death sentence.**

23 94. Plaintiff incorporates by reference each and every statement and allegation set
 24 forth throughout this Complaint as if fully rewritten.

25 95. Defendants' refusal to provide Plaintiff with information that would enable him
 26 to determine whether the State intends to execute him in compliance with requirements
 27 set forth in the execution protocol, DO 710, denies him his First Amendment right of
 28 access to governmental proceedings. *See Cal. First Amendment Coal. v. Woodford*, 299
 F.3d 868, 873 (9th Cir. 2002) ("It is well settled that the First Amendment guarantees the
 public—and the press—a qualified right of access to governmental proceedings."); *id.* at

1 875 (noting that the public's First Amendment right of access to governmental
 2 proceedings extends to executions); *id.* at 876 ("To determine whether lethal injection
 3 executions are fairly and humanely administered, or whether they ever can be, citizens
 4 must have reliable information about the initial procedures, which are invasive, possibly
 5 painful and may give rise to serious complications." (internal quotations omitted)).

6 **Claim Two: Defendants' refusal to provide information regarding the BUD of**
 7 **the compounded drug intend for use in his execution denies Plaintiff his federal**
 8 **rights to due process under the Fourteenth Amendment.**

9 96. Plaintiff incorporates by reference every statement and allegation set forth
 10 throughout this Complaint as if fully rewritten.

11 97. The Fourteenth Amendment prohibits a state from depriving "any person of life,
 12 liberty, or property, without due process of law[.]" U.S. Const. amend XIV.

13 98. Plaintiff has a liberty interest in assuring that his execution is carried out in a
 14 manner consistent with the requirements of the execution protocol, DO 710 and the
 15 Eighth Amendment.

16 99. By deliberately concealing information from Plaintiff, Defendants have actively
 17 prevented Plaintiff from to making a valid assessment of whether he will be executed in
 18 a manner consistent with the execution protocol, DO 710, and his Eighth Amendment
 19 rights. Therefore, Defendants' actions have violated Plaintiff's rights to due process
 20 guaranteed by the Fourteenth Amendment.

21 **Prayer For Relief**

22 WHEREFORE, Plaintiff prays for:

- 23 1. Temporary, preliminary, and permanent injunctive relief to enjoin the
- 24 Defendants, their officers, agents, servants, employees, and all persons from
- 25 executing Plaintiff until Defendants have provided information, including
- 26 supporting testing data that demonstrates the compounded pentobarbital has been
- 27 assigned a BUD or expiration date beyond the date of his scheduled execution,
- 28 information necessary to ensure his First Amendment right of access to

1 governmental proceedings and in accordance with his due process rights under the
2 Fourteenth Amendment.

3 2. Appropriate and necessary discovery and an evidentiary hearing to permit
4 Plaintiff to prove his constitutional claims; and

5 3. Any such other relief as this Court deems just and proper.

6 Respectfully submitted this 3rd day of May, 2022.

7
8 Jon M. Sands
9 Federal Public Defender
District of Arizona

10 Jennifer M. Moreno
11 Therese M. Day
12 Amanda C. Bass
13 Assistant Federal Public Defenders

14 s/ Jennifer M. Moreno
15 Counsel for Petitioner
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